CENTER FOR DRUG EVALUATION AND RESEARCH

APPROVAL PACKAGE for:

APPLICATION NUMBER: 085981

TRADE NAME: Hydrocortisone acetate powder

GENERIC NAME: Hydrocortisone acetate powder

SPONSOR: Pharm-Tek, Inc.

APPROVAL DATE: 05/09/78

MAY 9 1978

NDA 85-981

Pharm-Tek, Inc.
Attention: Dan J. Badia
P.O. Box AB
Huntington, NY 11743

Gentlemen:

Reference is made to your abbreviated new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for Hydrocortisone Acetate Powder.

We have completed the review of this abbreviated new drug application and have concluded that the drug is safe and effective for use as recommended in the submitted labeling. Accordingly, the application is approved.

Any significant change in the conditions outlined in this abbreviated new drug application, requires an approved supplemental application before the change may be made, except for changes made in conformance with other provisions of Section 314.8 of the new drug regulations.

This Administration should be advised of any change in the marketing status of this drug.

The requirement for adequate data to assure the biologic availability is being deferred at the present time. However, our action in approving this application is based upon an understanding that if this requirement is reinstated you will perform the appropriate procedures.

Promotion of a product marketed under an abbreviated new drug application must not convey the impression that the product is a new entity.

The enclosures summarize the conditions relating to the approval of this application.

Sincerely yours,

Martin Seife, M.D.
Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs

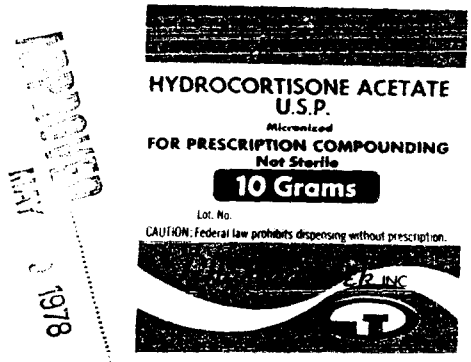
NYK-DO DUP HFD-614
REBarzilai/JLMeyer/CMSmith
R/DinitJMeyer/MSeife
ft/cjb/5-8-78 approved

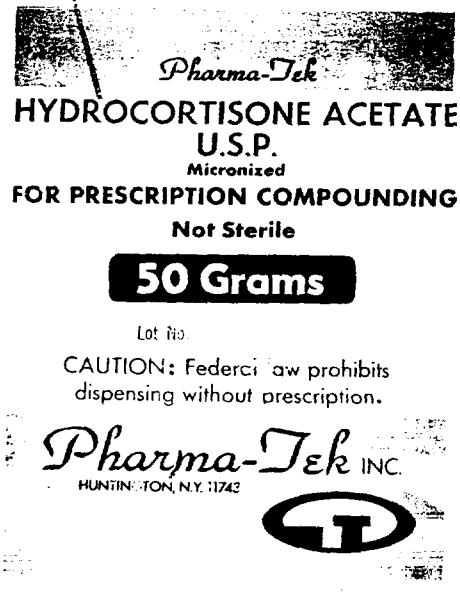
Enclosures:
Conditions of Approval of a New Drug Application
Records and Reports Requirements

ITEM 4

LABEL AND ALL OTHER LABELING

HYDROCORTISONE ACETATE USP FOR PRESCRIPTION COMPOUNDING





The statement "Micronized" to be replaced by the term "Milled" when used accordingly.

The appropriate lot number will be imprinted on each label at the time of a labeling of the batch.

NOTICE OF APPROVAL
NEW DRUG APPLICATION OR SUPPLEMENT

NDA NUMBER: 35-981

DATE APPROVAL LETTER ISSUED

TO: Press Relations Staff (HFI-40)

FROM:
- [x] Bureau of Drugs
- [ ] Bureau of Veterinary Medicine

MAY 3 1978

ATTENTION

Forward original of publication only after approval letter has been issued and the date of approval has been

ORIGINAL ABBREVIATED

TYPE OF APPLICATION
- [ ] ORIGINAL NDA
- [ ] SUPPLEMENT TO NDA
- [ ] ABBREVIATED ORIGINAL NDA
- [ ] SUPPLEMENT TO ANDA

CATEGORY
- [x] HUMAN
- [ ] VETERINARY

TRADE NAME (or other designated name) AND ESTABLISHED OR NONPROPRIETARY NAME (if any) OF DRUG
Hydrocortisone Acetate

DOSAGE FORM: Powder

HOW DISPENSED
- [x] Rx
- [ ] OTC

ACTIVE INGREDIENT(S) (as declared on label. List by established or nonproprietary name(s) and include amount(s), if amount is declared on label.)

Hydrocortisone Acetate

NAME OF APPLICANT (Include City and State)

Pharma-Tek
Huntington, NY 11743

PRINCIPAL INDICATION OR PHARMACOLOGICAL CATEGORY
Glucocorticoid

COMPLETE FOR VETERINARY ONLY

ANIMAL SPECIES FOR WHICH APPROVED

COMPLETE FOR SUPPLEMENT ONLY

CHANGE APPROVED TO PROVIDE FOR

FORM PREPARED BY

NAME: C M Smith

DATE

FORM APPROVED BY

NAME: J LMeyer

DATE

FORM FD 1642 (2/75) PREVIOUS EDITION MAY BE USED UNTIL SUPPLY IS EXHAUSTED.

CHEMIST's REVIEW FOR NEW DRUG APPLICATION OR SUPPLEMENT	Statement Date:	NDA NUMBER: 85-981

NAME AND ADDRESS OF APPLICANT

Pharma-Tek Inc. (Repackager for prescription Compounding)
Huntington, NY 11743

ORIGINAL
AMENDMENT
SUPPLEMENT
RESUBMISSION
CORRESPONDENCE
REPORT
OTHER

PURPOSE OF AMENDMENT/SUPPLEMENT

DATE(s) of SUBMISSION(s)
7/19/77, 9/15 1/11

PHARMACOLOGICAL CATEGORY	NAME OF DRUG	HOW DISPENSED
Glucocorticoid	Hydrocortisone Acetate	RX X OTC ____
DOSAGE FORM(S) Powder (Bulk for prescription compounding)	POTENCY(IES)	RELATED IND/NDA/DMF 85-982
STERILIZATION	SAMPLES	

LABELING

Satisfactory per RBarzilai

BIOLOGIC AVAILABILITY

deferred

ESTABLISHMENT INSPECTION

Applicant and testing labs in compliance, memo fr HFD-322 dated May 2, 1978

COMPONENTS, COMPOSITION, MANUFACTURING, CONTROLS

Controls are satisfactory

PACKAGING

Satisfactory

STABILITY

Protocol: Submitted, 3yr data. Applicant's supplier is ...ith 60-month expiration dating

Exp. Date: 36 months (D.O.D. request)

REMARKS AND CONCLUSION:

approval
CMSmith

Approved 5-8-78

MEMORANDUM

DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE
PUBLIC HEALTH SERVICE
FOOD AND DRUG ADMINISTRATION

TO : Director, Division of Generic Drug Monographs (HFD-530)
Attn: C. Smith

DATE: May 2, 1978

FROM : Chief, Manufacturing Review Branch (HFD-322)
Division of Drug Manufacturing

SUBJECT: Approvable ANDAs 85-981, Hydrocortisone Acetate for Prescription Compounding
85-982, " for Prescription Compounding

APPLICANT/REPACKER: Pharma-Tek, Inc.
Northport, N. Y.

We have re-evaluated the operations of Pharma-Tek, Inc. as they relate to compliance with Current Good Manufacturing Practice Regulations (21 CFR 211) and the referenced New Drug Applications.

Following our previous memo of 1/4/78 recommending non-approval of these two ANDAs due to lack of stability data, the applicant submitted amendments dated 1/11/78 to both applications with certain stability data and proposed 36 month expiration dates.

Based on this data, we have no further objection to approval of these ANDAs insofar as CGMP compliance of this firm is concerned, as long as your office deems the stability data sufficient in support of the 36 month expiration period.

David H. Bryant

David H. Bryant

cc: NYK-DO (HFR-2100)
HFV-234
HFD-530 (2)
HFD-322 Firm File
HFD-300 R/F
HFD-530 (ANDA Orig)
WABrown:rdj:5/2/78

NDA 85-981

Pharma-Tek, Inc.
Attention: Dan J. Badia
P.O. Box AB
Huntington, NY 11743

Gentlemen:

Reference is made to your abbreviated new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug and cosmetic Act for Hydrocortisone Acetate USP for Prescription Compounding.

Reference is also made to your communications dated September 15, 1977 and January 11, 1978, amending the application.

We have completed the review of this abbreviated new drug application. However, we are unable to make a final decision at this time.

We call your attention to the report of inspection of your facilities conducted on September 8, 1977, which indicated disagreement between actual current good manufacturing practices (CGMP) and the commitment in your application.

Therefore, before we can take further action on this application, we should have a satisfactory inspection report from our Bureau of Drugs, Division of Drug Manufacturing.

We will communicate with you after we have received this report.

Sincerely yours,

Marvin Seife 3/2/78

Marvin Seife, M.D.
Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs

NYK-DO
HFD-614
RBarzilai/JLMeyer/CMSmith
R/D init JLMeyer/MSeife/2-23-78
mlb/2-23-78
rev w/f

REVIEW OF ANDA'S

DATE COMPLETED: 8-10-77

ANDA #: 85-981
85-982

CO. NAME: Pharma-Tek, Inc.

NAME OF DRUG: 85-981 Hydrocortisone Acetate USP

85-982 Hydrocortisone USP

DATE OF SUBMISSION: 7-19-77

TYPE OF SUBMISSION: ANDA's - both above products are "FOR PRESCRIPTION COMPOUNDING"

CLINICAL EVALUATION:

1. Review of Studies:

   Bio studies - deferred
   EIAR - for review by assigned chemist.

2. Review of Labeling: Acceptable FPL for non-sterile containers of 10 and 50 gm adequately labeled "FOR PRESCRIPTION COMPOUNDING". These products require no package insert since they are to be used only by registered pharmacists for "prescription compounding".

CONCLUSION: Acceptable FPL of container labels.

RECOMMENDATIONS: Needs chemists review.

R. Barzilai

R. Barzilai, M.D.

cc:dup
REB/wlb/8-10-77

ABBREVIATED NEW DRUG APPLICATION OR SUPPLEMENT	STATEMENT DATE	NDA NUMBER
		85-981

NAME AND ADDRESS OF APPLICANT (CITY AND STATE)

Pharma-Tek Inc
Huntington NY 11743

Original
Amendment
Supplement
Resubmission
Correspondence
~~Report~~
Other

Purpose of Amendment/Supplement

Date(s) of Submission(s)
7/19/77
9/15/77
1/11/78

Pharmacological Category	Name of Drug	
Glucocorticoid	Hydrocortisone Acetate	
Dosage Form(s)	Potency(ies)	~~How Dispensed~~ Rx OTC
Bulk for prescription	NA	
Packaging/Sterilization	Samples	Related IND/NDA/MF

Labeling

satisfactory per REBarzilai

Biologic Availability

deferred

Establishment Inspection

Applicant not in compliance @ 9/8/77
Re=inspection requested 2/16/78

Components, Composition, Manufacturing and Controls

Unsatisfactory

Remarks

Rev w/f
CMSmith

Conclusion

Reviewer

Date

Jackie Corbett 3-1-78
for

MEMO RECORD	AVOID ERRORS PUT IT IN WRITING	DATE 8-8-77
FROM: C. Smith (thru J.L. Meyer)		OFFICE HFD-530
TO: Mr. David H. Bryant, Office of Compliance		DIVISION HFD-322

SUBJECT: Inspection Request

SUMMARY

In conncetion with ANDA 85-981; 85-982

for: Hydrocortisone Acetate U.S.P. for prescription Compo

Applicant:

Pharma-Tek, Inc.
4 York Court
Northport, NY 11768

AF -

REQUESTED:

[✓] 1. Evaluation of compliance with CGMP for:

[✓] a. The applicant

[✓] b. Others See below

[✓] 2. Recommendation for approval/disapproval of the application/communication/supplement, based on your evaluation of compliance with CGMP

REMARKS: The following laboratories will be utilized for the testing of this product:

SIGNATURE	DOCUMENT NUMBER
C. Chang	85-981, 85-982

NDA 85-981

AUG - 5 1977

Pharma-Tek, Inc.
Attn: Dan J. Badia
P.O. Box AB
Huntington, NY 11743

Gentlemen:

We acknowledge the receipt of your abbreviated new drug application submitted pursuant to Section 505(b) of the Federal Food, Drug, and Cosmetic Act for the following:

NAME OF DRUG: Hydrocortisone Acetate USP for Prescription Compounding

DATE OF APPLICATION: July 19, 1977

DATE OF RECEIPT: August 2, 1977

We will correspond with you further after we have had the opportunity to review the application.

Please identify any communications concerning this application with the NDA number shown above.

Sincerely yours,

NYK-DO DUP HFD-614
JLMeyer/cjb/8-4-77 ack

JLMeyer 8/4/77

Marvin Seife, M.D. 8/5/77
Director
Division of Generic Drug Monographs
Office of Drug Monographs
Bureau of Drugs